REMARKS

In the Office Action mailed September 18, 2008, the Examiner noted that the Information Disclosure Statement filed with the Application on April 28, 2006, failed to comply with 37 C.F.R. 1.98(a)(2). However, the only references cited in that Information Disclosure Statement were the references that are cited in the International Search Report of this Section 371 national stage application. WIPO was charged with the duty to send a copy of the International Search Report and copies of the references cited therein to the USPTO to be associated with this application, and even though Applicant submitted a copy of the International Search Report with the Application at the time of filing, Form PCT/DO/EO 903 did not indicate any documents in the national stage file but those that were submitted by the Applicant at the time of filing. Applicant is therefore uncertain whether the International Search Report and the copies of the references cited therein were ever submitted by WIPO to the USPTO, or if they were in fact sent to the USPTO, whether they have been associated with this file. Applicant requests the Examiner's cooperation in determining whether or not WIPO did send a copy of the International Search Report and copies of the references cited therein to the USPTO that have not yet been associated with this file. Under MPEP §1893.03(g), Applicant's only duty should have been the submission of the listing of the prior art references cited in the International Search Report on a Form PTO/SB/08A. Should the Examiner confirm that the International Search Report and copies of the references cited therein were never provided by WIPO to the USPTO, Applicant will obtain copies of the non-patent references and submit them in a Supplemental Information Disclosure Statement, promptly.

Applicant also notes the Examiner's suggestions for the arrangement of the Specification, and Applicant will make all Section headings to the Specification when allowable subject matter is indicated to be present in the present Application.

Turning now to the claim rejections, claims 1-4 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention, for the specific reasons set forth on pages 5-6 of the Office Action mailed September 18, 2008. By the foregoing proposed claim amendments, the Examiner will please note that the Applicant has addressed and remedied all of the deficiencies in claims 1-4 that gave rise to their rejections under 35 U.S.C. §112, second paragraph. These §112 rejections are thus deemed to be moot.

Turning now to the prior art claim rejections, claims 1-2 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bloukas et al. in view of the combination of Domazakis and "Sonoma sausage." Claims 3-4 have been rejected under 35 U.S.C. §103(a) as being unpatenable over Bloukas et al. in view of the combination of Domazakis and "Sonoma sausage," and further in view of Gryczka et al. For the reasons that follow, Applicant traverses all of these prior art base grounds for rejecting the claims of the present Application.

One important feature that clearly differentiates the methods and resulting meat products of the present invention from the prior art of record is the principle served by the present invention. The Applicant has made no attempt to alter, by any means, the natural liquid states of the critical ingredients, as did Bloukas. It is the ultimate goal of the present invention to keep the natural liquid state of the critical ingredients as natural as they can be, and thus, more particularly, to protect and maintain the natural liquid state of olive oil, which can only be accomplished using the noted and careful methodology of the present invention.

The Examiner should notice that the methods for producing the fermented meat products of the present invention is complicated and clearly differentiated from the cooked meat emulsion methods of the prior art. The Applicant was unexpectedly led to the resulting products of the present invention by exploiting a process that relies only upon emulsification and physical entrapment events. Emulsification events occur in the interface of olive oil globules/meat protein/fat particles/and water. Physical entrapment events occur throughout the protein matrix. Finally, by using the bio-fermentation and desiccation procedures of the present invention, stable, no-fat exudating meat products incorporating olive oil are produced. The Applicant provided ranges of specific factors (i.e., temperature, relative humidity), that impose conditions favorable to the development of the specific meat products of the present invention.

In the fermented meat producing methods of the present invention, the combined effect of emulsification and physical entrapment become the driving forces of fat incorporation, in direct contrast with the cooked meat emulsion systems of the prior art in which mainly emulsification is relied upon, is greatly enhanced, and is promoted. In the prior art, parameters promoting emulsification include: i) the high meat comminution and ii) the addition of non-meat emulsifying agents. Both of the aforementioned emulsification enhancing factors present in the prior art are absent from the present invention.

Clear problems have been associated with the stable incorporation of vegetable oil in the fermented meat producing methods of the prior art that rely upon emulsification alone. In this regard, Bloukas observes,

> "the way of incorporating the olive oil in the meat mixture significantly affected the sensory evaluation. The appearance of fermented sausages

produced by direct incorporation of olive oil as liquid was rather unacceptable. The casings were separated from the sausages and liquid fat collected under the casings." (page 141).

In the "Conclusion" of the Bloukas reference (page 143), Bloukas also says the following: "the direct incorporation of olive oil results in fermented sausages with an unacceptable appearance and very soft texture." Bloukas, in other words, underlines the prior art problem of exudation and non-stable incorporation of the olive oil fat into the meat mixture. Bloukas concludes that only the indirect olive oil incorporation (use of pre-emulsified fat) was successful in obtaining the desired quality characteristics. To achieve this, Bloukas used soy protein isolate as a pre-emulsifying agent to enable the olive oil to be added.

Domazakis, on the other hand, deals only with cooked meat emulsion-based systems, and also discloses a combination of non-meat emulsifying additives, which are necessary according to Domazakis to facilitate the stable incorporation of olive oil in the meat paste (-batter). Therefore, it would have only been obvious to one of ordinary skill in the art at the time of the present invention to modify Bloukas in view of Domazakis, by selecting a non-meat additive from Domazakis to incorporate olive oil, as a substitute for those suggested by Bloukas (i.e. soy protein).

By direct contrast, the present Applicant makes no use of non-meat emulsifying agents in the present application to successfully incorporate olive oil. This clearly differentiates the methods and resulting meat products of the present invention from the known prior art, by successfully modifying the ingredients list and the processes these ingredients are subjected to. Moreover, the Applicant could not have been motivated by Bloukas to proceed along the lines of the present invention, as Bloukas clearly and explicitly discourages a person of ordinary skill

from proceeding with the development of a dry fermented meat product incorporating olive oil without the addition of extra emulsifying additives.

The Applicant reached the unexpected favorable results of the present invention by a combination of approaches, which are briefly described below.

1. The utilization of enhanced extraction of salt soluble meat proteins (SSMP) for maximizing the retention capability of the meat mixture. As chopping progresses, the particle reduction process rapidly increases the surface area of the fat particles. Therefore, more protein is required to form the protein layer that surrounds the fat globules. The Applicant elongates the time of exposure of the meat matrix to salt by adding the salt at the initial mixing stage, and thus improves protein solubilization. The addition of salt at an earlier stage of the process enhances the extraction of SSMP and their free availability in the meat mixture. In this way, the fat particles seem to be sufficiently coated and stabilized in the resulting product. To the contrary, Bloukas specifically mentions that the addition of salt takes place at a stage subsequent to initial mincing. (page 135).

2. The Applicant also selected the suitable starting temperatures that unexpectedly produced favorable effects.

By contrast, Bloukas, it is stated, "the frozen beef and pork meat were cut and pre-weighed amounts of beef and pork meat were chopped for 2-3 sec." (page 135). Therefore, it would indeed be obvious and predictive for a person of ordinary skill to select any temperature in a broad range (+/- 5 degrees °C) around the freezing temperature of -20°C taught in Bloukas. However, the specified starting temperature of -4°C of the present invention is clearly higher than the recommended temperature range taught by Bloukas.

Domazakis, on the other hand, selects even higher temperature values at the process milestones. Specifically, thin meat at a temperature 0°C is mixed with a number of ingredients that are conventionally stored at room temperature, such as vegetable proteins, milk proteins and starch, the exception being water of -2°C. The addition of olive oil occurs at a mixture temperature of 2 °C, and the mixing process stops when the temperature is 4°C. In the present invention, by contrast, the starting temperature is -4°C and the addition of olive oil occurs at a mixture temperature -2°C, i.e. 4 degrees lower than Domazakis. Chopping, as a mechanical mechanism, decreases the surface tension on the fat particles, thus preventing the formation of large fat globules and thus facilitates their physical entrapment as well as the emulsification phenomena to a degree necessary for the stable retention of the oil phase by the protein matrix.

A further detailed comparison between the present invention and the Bloukas (R1) and the Domazakis (R2) references is shown in the table below.

The Applicant strongly believes that the successful processing methods of the present application for the incorporation of olive oil in a ready to consume meat product is attributed to the novel combined claimed effects of both emulsification and the physical entrapment events, under the claimed ranges of ripening/drying conditions, and all <u>without</u> the need of an extra emulsifier either of vegetable (isolated Soy Protein) or animal origin (caseinates).

	Present Invention	**Bloukas et al (R1)**	**Domazakis 2001 (R2)**
Raw materials and starting temperatures			
Type of meat product	Dry and Semi-dry	Dry only	Cooked
Type of meat raw materials	Fatless skeletal (bone and muscle) tissue; <u>Distinguishable feature:</u> Free	Defatted Beef and Pork meat	Thin-chopped non-fat meat

	choice of meat source. Developed to include skeletal tissue from various edible animal species, wherever applicable.		
Type of animal fat	Pork fat	Pork fat	No animal fat added
Type of vegetable oil in substitution of the animal fat	Liquid Olive oil	L treatments: liquid olive oil E treatments: pre-emulsified olive oil	Liquid olive oil
Target amount of total added fat in the end product	<10 %	33% total fat (10%-20% olive oil participation)	Not stated
Type of added emulsifier used	None	*L treatments:* None *E treatments:* Soy protein	Vegetable proteins, Milk Proteins
Critical Parameter 1 Selected starting temperatures	Meat at -4°C. Addition of liquid olive oil (liquid up to ca -5 °C) and fat particles when paste reaches -2C	Frozen beef and pork meat (Specified temperature: -20°C)	Meat at 0°C. Addition of liquid olive oil (liquid up to ca -5 °C) when paste reaches 2°C.
Mixing and Chopping Process			
Critical parameter 2 Incorporation of vegetable oil	Direct incorporation of liquid olive oil	*L treatments:* Direct incorporation of liquid olive oil. No temperature for addition stated. (processing conditions followed did not result to stable incorporation, see below) *E treatments:* Indirect incorporation of pre-emulsified olive oil Distinguishable feature: Oil in water emulsion (O/W), protein isolate as an emulsifier, leading to a composed, extra ingredient, secondly entrapped in the meat matrix .	Direct incorporation of liquid olive oil
Critical parameter 3 Salt addition stage	Salt added *simultaneously* with the meat tissue and other solid auxiliary ingredients, *before* the addition of the fat phase.	Salt is added *last* into the meat emulsion, following meat mincing, addition of fat phase and solid auxiliary ingredients. "The frozen beef and pork meat were cut and pre-weighed	Salt added *simultaneously* with the meat tissue *before* other solid auxiliary ingredients are added.

		amounts of beef and pork meat were chopped for 2-3 sec (....) at low speed and mixed with other ingredients, except sodium chloride. The pork backfat and the olive oil, either as liquid or as pre-emulsified fat, was added and the meat mixture was chopped for 2-3s. The cup of the the cutter was cleaned, sodium chloride added and the meat mixture was chopped at low speed to the desired particle size (...) (page 135)	
1) Mixing / chopping time 2) Particle size , Sausage dimension/ weight 3) Application	1) Mixing and chopping time depending on desired meat- and - fat particle size . 2) Mixing of paste upon addition of olive oil from **-2°C till the desired grain size is achieved.**	1) Desired particle size (3-5 mm). 2) Method applicable only for one type of sausage (47 mm diameter, weight 1-1,5 Kg) 3) Method provides a special technological approach, covering only one type of sausage and leading to a product which provides strictly specified intended attributes.	1) Mixing of paste upon addition of olive oil from **2°C** until 4°C.
Initial Fermentation Chambers			
Initial fermentation conditions	**Dry:** *Time:* depending on the product size, cultures, (regulated by the person skilled in the art) *Temperature:* 25-20 °C, *RH:* 95-80%, *Air velocity:* 0.5-0.8 m/sec **Semi-dry**: 24-30 hours at 25-30°C, 75% - 60% RH, 0.5-0.8 m/sec air velocity	*Time:* 5 days, *Temperature:* 20.5-15 °C, *RH*: 95-80% *Air velocity:* 0.5-07 m/sec	Not applicable
Heat Processing (applicable only to Semi-dry)			
Temperatures and time intervals	Heated to obtain 55°C core temperature *Time:* 0.5-2 hours, depending on product diameter	*Not Valid for Bloukas et al*	Heated at 71°C Time: depending on the diameter of the product
Final Fermentation Chambers			
Final fermentation conditions	**Dry**: *Time:* until desired dehydration, colour, odour and	*Time:* 6-30 days *Temperature:* 15°C *RH:* 80%,	Not applicable

	flavour are obtained *Temperature:* 12-17°C *RH:* 80-75%, *Air velocity:* 0.5-0.1 m/sec	*Air velocity:* 0.05-0.1 m/sec	
	Semi-dry: *Time:* until desired dehydration, colour and flavour are obtained *Temperature:* 12-17°C *Air velocity:* 0.5-0.1 m/sec *RH:* 80-75%		

For all these foregoing reasons, Applicant respectfully requests entry of the foregoing amendments, reconsideration of the present Application in light thereof and in light of the foregoing remarks, and an allowance of claims 1-4, as amended, over all the prior art of record.

Respectfully submitted,

By: _____

Clifford W. Browning
Reg. No. 32,201
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, IN 46204
(317) 238-6203